IN THE CLAIMS

I. Addition of Claims

Please add new claims 146-152 as set forth below in the complete listing of all pending claims.

1. (Previously Amended) A method of treating hypogonadism in a male subject in need thereof, comprising administering a composition to a selected area of skin of the male subject in a pharmacologically effective amount to treat the hypogonadism, wherein the composition consists essentially of:

a) about 0.5 % to about 10 % testosterone;

b) about 30 % to about 98 % alcohol selected from the group consisting of ethanol, and isopropanol;

c) about 0.1 % to about 5 % isopropyl myristate;

d) about 1 % to about 5 % 0.1 N sodium hydroxide; and

e) about 0.1 % to about 5 % gelling agent; and

wherein the percentages are weight to weight of the composition, and the testosterone is absorbed into the bloodstream of the subject at a rate and duration that maintains a circulating serum concentration of the testosterone greater than about 400 ng testosterone per dl serum during a time period beginning about 2 hours after administration and ending about 24 hours after administration.

2. The method of claim 1, wherein the composition is administered daily for at least about 7 days.

3. The method of claim 1, wherein the composition is administered daily for at least about 30 days.

4. The method of claim 1, wherein the composition is administered daily for at least about 180 days.

5. The method of claim 1, wherein the administration of the composition exhibits dose proportionality.

6. The method of claim 1, wherein the administration results in a steady-state testosterone 24-hour pharmacokinetic profile in the male subject, having an increase in circulating serum concentration of the testosterone greater than about 400 ng testosterone per dl serum at about two hours after administration followed by a decrease to a testosterone concentration that remains relatively constant for the remainder of the day.

7. The method of claim 6, wherein the composition is administered daily for at least about 7 days.

8. The method of claim 6, wherein the relatively constant testosterone serum concentration is between about 400 ng/dL and about 1,000 ng/dL.

9. The method of claim 1, wherein the administration causes an increased average dihydrotestosterone serum concentration in the male subject.

10. The method of claim 1, wherein the administration causes an increase in the bone mineral density of the male subject.

11. The method of claim 10, wherein the increase in the bone mineral density occurs in the spine and/or hip.

12. The method of claim 1, wherein the administration causes increased libido in the male subject.

13. The method of claim 1, wherein the administration causes improved sexual performance in the male subject.

14. The method of claim 13, wherein the improved sexual performance comprises an increase in the percentage of full erection by the male subject.

15. The method of claim 1, wherein the administration causes improved mood in the male subject.

16. The method of claim 1, wherein the administration causes increased muscle strength in the male subject.

17. The method of claim 16, wherein the increased muscle strength occurs in the legs of the male subject.

18. The method of claim 1, wherein the administration causes improved body composition in the male subject.

19. The method in claim 18, wherein the improved body composition comprises a decrease in the fat percentage of the male subject.

20. The method of claim 1, wherein the administration causes negligible skin irritation.

21. The method of claim 1, wherein the testosterone C_{max} and C_{min} is within the normal range of an eugonadal male subject.

22.-26. (Cancelled)

27. The method of claim 1, wherein the testosterone comprises an enantiomer, a racemic mixture, a derivative, a base, or a salt thereof.

28-52. (Cancelled)

53. The method of claim 1, wherein the composition administered weighs about 1.0 gram to about 10 grams.

54. The method of claim 1, wherein the composition administered weighs about 2.5 grams to about 7.5 grams.

55. The method of claim 1, wherein the composition administered weighs about 2.5 grams to about 5.0 grams.

56. (Cancelled)

57. The method of claim 1, wherein the composition comprises about 0.5 % to about 5 % testosterone.

58. The method of claim 1, wherein the composition comprises about 1 % testosterone.

59. (Cancelled)

60. The method of claim 1, wherein the composition comprises about 0.25 % to about 2.5 % isopropyl myristate.

61. The method of claim 1, wherein the composition comprises about 0.5 % isopropyl myristate.

62. The method of claim 1, wherein the gelling agent is polyacrylic acid.

63. The method of claim 62, wherein the composition comprises about 0.9 % polyacrylic acid.

64. The method of claim 1, wherein the composition comprises about 40 % to about 90 % alcohol.

65.-78. (Cancelled)

79. The method of claim 86, wherein the packet comprises a polyethylene liner between the composition and inner surface of the packet.

80. The method of claim 1, wherein the serum testosterone concentration is maintained between about 400 ng testosterone per dl serum to about 1050 ng testosterone per dl serum.

81. The method of claim 1, wherein for each about 0.1 gram per day administration of the composition to the skin, an increase of at least about 5 ng/dl in serum testosterone concentration results in the subject.

82. The method of claim 1, wherein the composition is provided to the subject for daily administration in a dose of approximately 0.1 g, 2.5 g, 5 g, 7.5 g, or 10 g.

83. The method of claim 82, wherein the dose is approximately a 5 g dose delivering about 50 mg to about 100 mg of testosterone to the skin.

84. The method of claim 82, wherein the dose is approximately a 7.5 mg dose delivering about 50 mg to about 100 mg of testosterone to the skin.

85. The method of claim 82, wherein the dose is approximately a 10 g dose delivering 50 mg to about 100 mg of testosterone to the skin.

86. The method of claim 82, wherein the composition is provided to the subject in one or more packets.

87. The method of claim 1, wherein maximum serum testosterone concentration in the subject is reached about 16 hours after administration of the composition on day one of administration.

88. The method of claim 1, wherein after at least about 30 days of daily administration serum testosterone concentration in the subject is at least about 490 ng/dl to about 860 ng/dl.

89. The method of claim 1, wherein after at least about 30 days of daily administration serum dihydrotestosterone concentration in the subject is greater than about 54 ng/dl.

90. The method of claim 1, wherein after at least about 30 days of daily administration a ratio of serum dihydrotestosterone concentration to serum testosterone concentration of greater than about 0.23 is achieved in the subject.

91. The method of claim 1, wherein after at least about 30 days of daily administration total serum androgen concentration in the subject is greater than about 372 ng/dl.

92. The method of claim 1, wherein after at least about 30 days of daily administration serum estradiol concentration in the subject is greater than about 28 pg/ml.

93. The method of claim 1, wherein the subject has primary hypogonadism prior to administration.

94. The method of claim 93, wherein after at least about 30 days of daily administration serum follicle stimulating hormone concentration in the subject is less than about 11 mIU/ml.

95. The method of claim 1, wherein the subject has secondary hypogonadism prior to administration.

96. The method of claim 95, wherein after at least about 30 days of daily administration serum follicle stimulating hormone concentration in the subject is less than about 3.7 mIU/ml.

97. The method of claim 1, wherein the subject has a pretreatment serum follicle stimulating hormone concentration greater than a normal range of a normal subject.

98. The method of claim 97, wherein after at least about 30 days of daily administration the serum follicle stimulating hormone concentration is within or below the normal range.

99. The method of claim 1, wherein the subject has a pretreatment serum luteinizing hormone concentration greater than a normal range of a subject having primary hypogonadism.

100. The method of claim 99, wherein after at least about 30 days of daily administration serum luteinizing hormone concentration is within the normal range.

101. The method of claim 101, wherein after at least about 30 days of daily administration the serum luteinizing hormone concentration is less than about 6.8 mlU/ml.

102. The method of claim 1, wherein after at least about 30 days of daily administration the testosterone has an accumulation ratio in the male subject greater than about 1.5.

103. The method of claim 1, wherein after at least about 30 days of daily administration the testosterone has a net AUC_{0-24} in the male subject greater than 220 nmol*h/l.

104. (Previously Amended) A method of treating hypogonadism in a male subject in need thereof, comprising:

(a) preparing a composition consisting essentially of:

1) about 0.5 % to about 10 % testosterone;

2) about 30 % to about 98 % alcohol selected from the group consisting of ethanol, and isopropanol;

3) about 0.1 % to about 5 % isopropyl myristate;

4) about 1 % to about 5 % 0.1 N sodium hydroxide; and

5) about 0.1 % to about 5 % gelling agent; and

(b) applying the composition to a selected area of skin of the male subject in an amount effective to treat the hypogonadism;

wherein the percentages are weight to weight of the composition.

105. The method of claim 104, wherein the composition is applied for at least about 7 days.

106. The method of claim 104, wherein the composition is applied for at least about 30 days.

107. The method of claim 104, wherein the composition is applied for at least about 180 days.

108. The method of claim 104, wherein the application of the composition exhibits dose proportionality.

109. The method of claim 104, wherein the testosterone comprises an enantiomer, a racemic mixture, a derivative, a base, or a salt thereof.

110. The method of claim 104, wherein the composition applied weighs about 1 gram to about 10 grams.

111. The method of claim 104, wherein the composition applied weighs about 2.5 grams to about 7.5 grams.

112. The method of claim 104, wherein the composition applied weighs about 2.5 grams to about 5 grams.

113. The method of claim 104, wherein the composition comprises about 0.5 % to about 5 % testosterone.

114. The method of claim 104, wherein the composition comprises about 1% testosterone.

115. The method of claim 104, wherein the composition comprises about 0.25% to about 2.5 % isopropyl myristate.

116. The method of claim 104, wherein the composition comprises about 0.5% isopropyl myristate.

117. The method of claim 104, wherein the gelling agent is polyacrylic acid.

118. The method of claim 117, wherein the composition comprises about 0.9 % polyacrylic acid.

119. The method of claim 104, wherein the composition comprises about 40% to about 90% alcohol.

120. The method of claim 104, wherein the testosterone is absorbed into the bloodstream of the subject at a rate and duration that maintains a circulating serum concentration of the testosterone greater than about 400 ng testosterone per dl serum during a time period beginning about 2 hours after application and ending about 24 hours after application.

121. The method of claim 104, wherein the serum testosterone concentration is maintained between about 400 ng testosterone per dl serum to about 1050 ng testosterone per dl serum during a time period beginning about 2 hours after application and ending about 24 hours after application.

122. The method of claim 104, wherein for each about 0.1g/day application of the composition to the skin, an increase of at least about 5 ng/dl in serum testosterone concentration results in the subject.

123. The method of claim 104, wherein the composition is provided to the subject for daily application in a dose of approximately 0.1 g, 2.5 g, 5 g, 7.5 g, or 10 g.

124. The method of claim 123, wherein the dose is approximately a 5 g dose delivering about 50 mg to about 100 mg of testosterone to the skin.

125. The method of claim 123, wherein the dose is approximately a 7.5 mg dose delivering about 50 mg to about 100 mg of testosterone to the skin.

126. The method of claim 123, wherein the dose is approximately a 10 g dose delivering 50 mg to about 100 mg of testosterone to the skin.

127. The method of claim 123, wherein the composition is provided to the subject in one or more packets.

128. The method of claim 127, wherein the packet comprises a polyethylene liner between the composition and inner surface of the packet.

129. The method of claim 104, wherein maximum serum testosterone concentration in the subject is reached about 16 hours after application of the composition on day one of administration.

130. The method of claim 104, wherein after at least about 30 days of daily application serum testosterone concentration in the subject is about 490 ng/dl to about 860 ng/dl.

131. The method of claim 104, wherein after at least about 30 days of daily application serum dihydrotestosterone concentration in the subject is greater than about 54 ng/dl.

132. The method of claim 104, wherein after at least about 30 days of daily application a ratio of serum dihydrotestosterone concentration to serum testosterone concentration of greater than about 0.23 is achieved in the subject.

133. The method of claim 104, wherein after at least about 30 days of daily application total serum androgen concentration in the subject is greater than about 372 ng/dl.

134. The method of claim 104, wherein after at least about 30 days of daily application serum estradiol concentration in the subject is greater than about 28 pg/ml.

135. The method of claim 104, wherein the subject has primary hypogonadism prior to application.

136. The method of claim 135, wherein after at least about 30 days of daily application serum follicle stimulating hormone concentration in the subject is less than about 11 mIU/ml.

137. The method of claim 104, wherein the subject has secondary hypogonadism prior to application.

138. The method of claim 137, wherein after at least about 30 days of daily application serum follicle stimulating hormone concentration in the subject is less than about 3.7 mIU/ml.

139. The method of claim 104, wherein the subject has a pretreatment serum follicle stimulating hormone concentration greater than normal range of a normal subject.

140. The method of claim 139, wherein after at least about 30 days of daily application the serum follicle stimulating hormone concentration is within or below the normal range.

141. The method of claim 104, wherein the subject has a pretreatment serum luteinizing hormone concentration greater than a normal range of a subject having primary hypogonadal.

142. The method of claim 141, wherein after at least about 30 days of daily application serum luteinizing hormone concentration is within the normal range.

143. The method of claim 141, wherein after at least about 30 days of daily application the serum luteinizing hormone concentration is less than about 6.8 mlU/ml.

144. The method of claim 104, wherein after at least about 30 days of daily application the testosterone has an accumulation ratio in the male subject greater than about 1.5.

145. The method of claim 104, wherein after at least about 30 days of daily application the testosterone has a net AUC_{0-24} in the male subject greater than 220 nmol*h/l.

146. (New) A method of treating hypogonadism in a male subject in need thereof, comprising administering a hydroalcoholic gel formulation to a selected area of skin of the male subject in a pharmacologically effective amount to treat the hypogonadism, wherein the formulation consists essentially of:

a. about 1% testosterone;

b. about 30% to about 98% ethanol;

c. about 0.1% to about 5% isopropyl myristate;

d. about 4.72% of 0.1 N sodium hydroxide;

e. about 0.1% to about 5% polyacrylic acid; and

f. water in an amount sufficient to make the formulation 100%;

wherein the percentages are weight to weight of the formulation; and

wherein the testosterone is absorbed into the bloodstream of the subject at a rate and duration that maintains a circulating serum concentration of the testosterone greater than about 400 ng testosterone per dl serum during a time period beginning about 2 hours after administration and ending about 24 hours after administration.

147. (New) The method of claim 146, wherein the daily administration of the formulation results in a steady-state serum concentration of testosterone of about 400 ng/dl to about 1,000 ng/dl.

148. (New) The method of claim 146, wherein the amount of polyacrylic acid is about 0.9%.

149. (New) The method of claim 146, wherein the amount of isopropyl myristate is about 0.5%.

150. (New) The method of claim 146, wherein the amount of ethanol is about 72.5% of a 95% (w/w) ethanol solution.

151. (New) The method of claim 146, wherein the amount of water is about 20%.

152. (New) A method of treating hypogonadism in a male subject in need thereof, comprising administering a hydroalcoholic gel formulation to a selected area of skin of the male subject in a pharmacologically effective amount to treat the hypogonadism, wherein the formulation consists essentially of:

a. about 1% testosterone;

b. about 72.5% of 95% (w/w) ethanol;

c. about 0.5% isopropyl myristate;

d. about 4.72% of 0.1 N sodium hydroxide;

e. about 0.9% polyacrylic acid; and

f. water in an amount sufficient to make the formulation 100%;

wherein the percentages are weight to weight of the formulation; and

wherein the testosterone is absorbed into the bloodstream of the subject at a rate and duration that maintains a circulating serum concentration of the testosterone greater than about 400 ng testosterone per dl serum during a time period beginning about 2 hours after administration and ending about 24 hours after administration.